

» Patent Literature and Methodology: WHO Model List of Essential Medicines

International Technology
Transfer Institute

The Franklin Pierce Center for
Intellectual Property, The
University of New Hampshire
School of Law



Presented By:
Dr. Stan Kowalski, Dr. Kevin Clark, Ian Mullet,
Spoorthy Gudavalli

UNIVERSITY of NEW HAMPSHIRE
SCHOOL of LAW



UNIVERSITY of NEW HAMPSHIRE
SCHOOL of LAW

- » Purpose
- » Background
- » Methodology
- » Results



» Purpose of this Project

- Develop methodology to assess the patent status of medicines on the WHO EML.
- Generate a detailed report for the public on the present (2010) patent status of medicines that were on patent in 2003 and those medicines added to the Model List since 2003 by country and level of development.
- Analyze patent trends of Essential Medicines by the development status of countries.



» Limited Scope of Methodology

- Companies that do not file U.S. patent applications will fall outside the search parameters of this report
- Many national jurisdictions have not made their patent information easily accessible through electronic resources making it difficult to ascertain patent filing trends for emerging economies.
- Engaging patent professionals in these jurisdictions may be necessary to research records in national patent offices
- Not comprehensive outside of current standardized available patent databases
 - Low patent information for non-reporting jurisdictions
 - Additional patents may have been available for evaluation but without the necessary time within which to consider them, they may have not been considered.
- The team did not do claim interpretation and cannot guarantee that the patents discovered were evaluated at the level of expert scientific sophistication to determine validity.



» Disclaimer

- This is an educational report and is neither inclusive nor comprehensive.
- Not a Freedom-To-Operate Analysis. In other words, one should NOT feel free to produce a medicine in a country simply because this report did not discover patent activity there.



- » Purpose
- » Background
- » Methodology
- » Results



Essential Medicines List (EML)

- Published by The World Health Organization
- What are Essential Medicines?
 - “Essential medicines are those that satisfy the priority health care needs of the population.”
 - Factors: Public Health Relevance, Evidence of Efficacy and Safety, and Comparative Cost Effectiveness
 - Essential Medicines List:
 - Guide for the development of national/institutional medicine lists
 - Tool for health equity
- Most current: March 2009, 16th Edition [Next Ed. March 2011]
 - Total Number of Medicines: 355 Medicines



Previous Assessment of EML

- “How do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries?”¹ -- Dr. Amir Attaran
 - Dr. Attaran’s Methodology



- This project covers Dr. Attaran’s researched medicines¹ and medicines added to the EML and Supplemental list since 2003.



¹ Amir Attaran, *How Do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries?* 23(3), *Health Affairs*, 155, 2004.

Medicines included in this Project

17 medicines¹
identified by Dr. Amir
Attaran in 2003

Since 2003, 67
additional medicines
were added by WHO to
the EML and the
supplemental list

A total of 84
medicines (17 + 67)
were included in this
project

77 medicines²
investigated

¹ Amir Attaran, *How Do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries?* 23(3), *Health Affairs*, 155, 2004.

² Seven medicines were removed due to their generalized nature. e.g. rehydration therapies and surfactants



- » **Background**
- » **Purpose**
- » **Methodology**
- » **Results**



» Basic Overview

Methodology for each medicine researched:

1. Find the expired or unexpired United States Base Patent
2. Find the expired or unexpired derivative patent(s) from the limited listings of US FDA Orange Book.¹
3. Collect the applications, grants, and other patent documents filed in foreign jurisdictions (i.e. patent families) related to the patents found above.
4. Generate world maps indicating patent filing trends.

¹ FDA requires reporting for the following patent types: medicine substance, polymorphs, formulation, composition, and method-of-use



» 1. Finding Base Patents

- What is a Base Patent?
 - Definition: The expired or unexpired patent for the active ingredient of the medicine.
- How to find a Base Patent:
 - Developed a decision tree protocol to systematically search various databases to efficiently find a base patent.
 - Examples of databases used: USPTO, Merck Index, FDA Orange Book



2. Finding Orange Book Patents

- What is the Orange Book?
 - A publication by the U.S. Food and Drug Administration (FDA)
 - Purpose: List all the medicine products approved by the FDA on the basis of safety and effectiveness in one place.
 - Also includes limited patent information
- Orange book information is available online



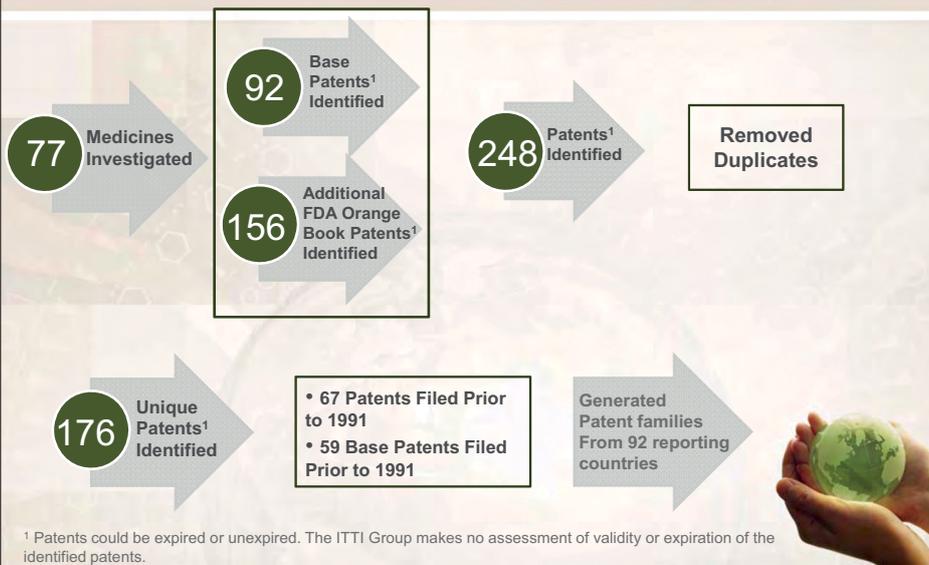
3. Finding Patent Families

- What is a Patent Family?
 - Definition: A collection of expired or unexpired documents from different countries, including patents, applications, and other materials, that are associated with a single parent patent.
- Three sets of family data created for each patent:
 - Derwent World Patent Index (DWPI) Family
 - International Patent Document (INPADOC) Family
 - LexisNexis TotalPatent Family
- Scope of family coverage:
 - 92 countries
 - Remember: There is no “international patent.” Patents are specific by country.



- » Background
- » Purpose
- » Methodology
- » Results

» Overview of Results





Example: Abacavir

Used to fight HIV infections in combination with at least two other antiretroviral medicines.

World Map Showing Abacavir Patent Filing Trends:



- 1 Base Patent
- 8 FDA Orange Patents
- 706 Family Documents
- 55 Reporting Countries



¹ Patents could be expired or unexpired. The ITTI Group makes no assessment of validity or expiration of the identified patents.

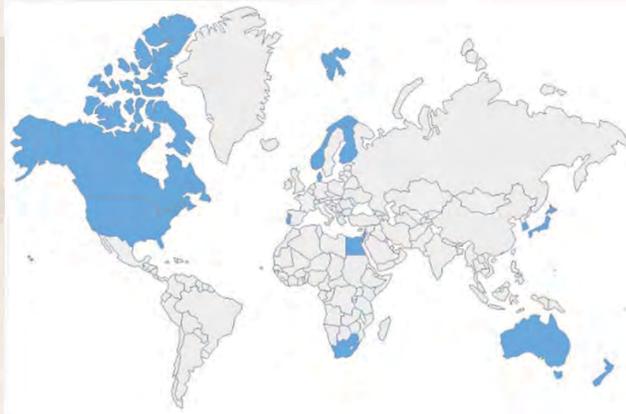
Geographic boundaries based on this map are not endorsed by authors or affiliates, and are merely used and presented for illustrative purposes.



Example: Stavudine

Used to fight HIV infections in combination with at least two other antiretroviral medicines

World Map Showing Stavudine Patent Filing Trends:



- 1 Base Patent
- 0 FDA Orange Patents
- 90 Family Documents
- 13 Reporting Countries



¹ Patents could be expired or unexpired. The ITTI Group makes no assessment of validity or expiration of the identified patents.

Geographic boundaries based on this map are not endorsed by authors or affiliates, and are merely used and presented for illustrative purposes.

Example: Stavudine

Used to fight HIV infections in combination with at least two other antiretroviral medicines

World Map Showing Stavudine Patent Filing Trends:



Example: Egypt

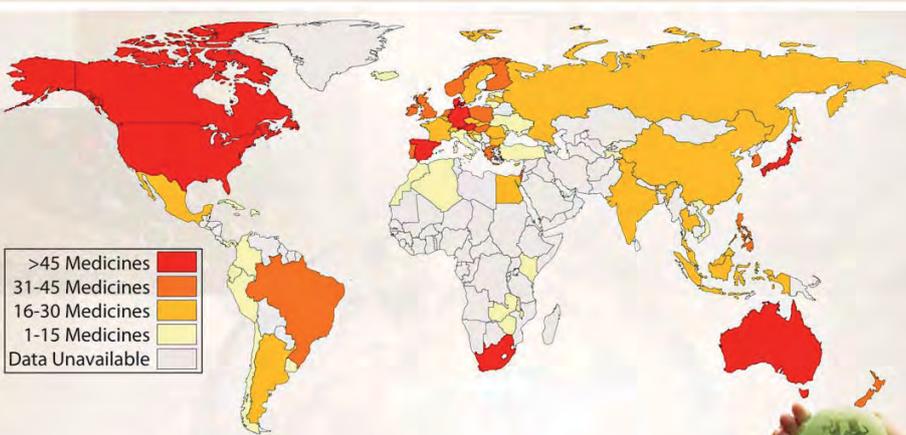
- Note family filing information from our analysis (country is flagged as possible patenting jurisdiction)
- Investigate INPADOC/WIPO Patent Family Legal Status
- Engage patent professional in Egypt to research records in national patent office.



¹ Patents could be expired or unexpired. The ITTI Group makes no assessment of validity or expiration of the identified patents.

Geographic boundaries based on this map are not endorsed by authors or affiliates, and are merely used and presented for illustrative purposes.

Patent Filing Trends - Jurisdictional



¹ Patents could be expired or unexpired. The ITTI Group makes no assessment of validity or expiration of the identified patents.

Geographic boundaries based on this map are not endorsed by authors or affiliates, and are merely used and presented for illustrative purposes.



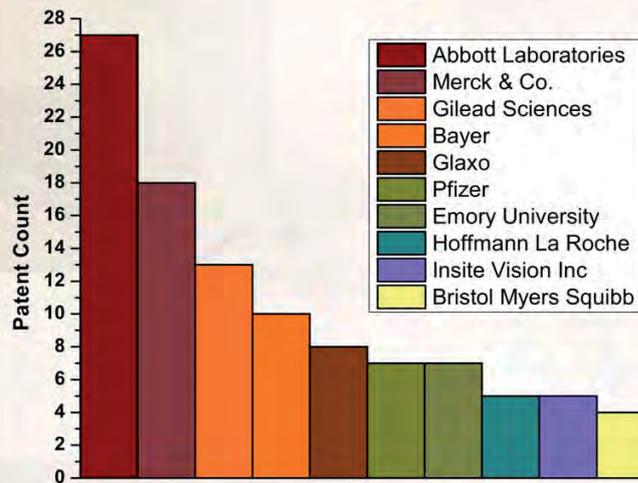
Patent Filing Trends – WHO Regions

WHO Region	Filings Per Region	Countries Per Region	Average Per Country
African Region	70	46	2
Eastern Mediterranean Region	30	21	1
European Region	992	53	19
Region of Americas	238	35	7
South East Asia Region	100	11	9
Western Pacific Region	318	27	12

¹ Patents could be expired or unexpired. The ITTI Group makes no assessment of validity or expiration of the identified patents.



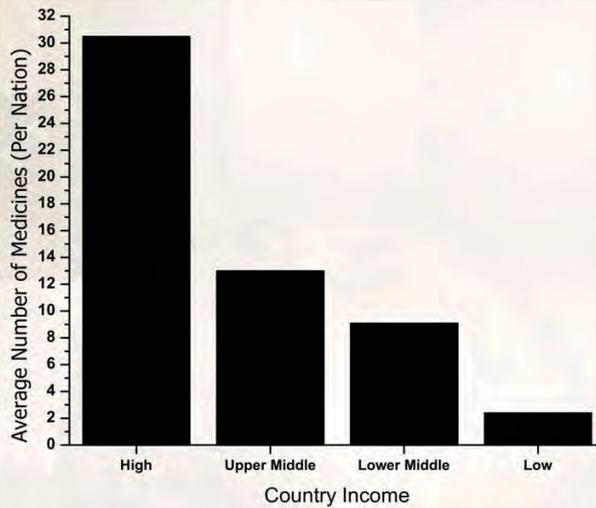
Top Companies



¹ Patents could be expired or unexpired. The ITTI Group makes no assessment of validity or expiration of the identified patents.



Medicines vs. Income



¹ Patents could be expired or unexpired. The ITTI Group makes no assessment of validity or expiration of the identified patents.

Thank You!!

**International Technology
Transfer Institute**

**The Franklin Pierce Center for
Intellectual Property, The
University of New Hampshire
School of Law**



Presented By:
**Dr. Stan Kowalski, Dr. Kevin Clark, Ian Mullet,
Spoothy Gudavalli**